| | | 7 |
|------|------|---|
| | | |
| | | |

PTO-1449 (Modified)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTY. DOCKET NO. 10361.49950

SERIAL NUMBER, 08/484,542

APPLICANT

Mark L. Braden, et al.

FILING DATE June 7, 1995

GROUP ART UNIT

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE |
|---------------------|--------------------|----------|--------------|-------|--------------|----------------|
| De College | 3,471,464 | 10/07/69 | Bellet | | | |
| DECIME | 3,528,960 | 09/15/70 | Haas | | | |
| | 3,591,574 | 07/06/71 | Fenichel | | | |
| | 3,752,798 | 08/14/73 | Amird | | | |
| | 3,755,569 | 08/28/73 | Fenichel | | | |
| | 3,823,125 | 07/09/74 | Grant | | | |
| | 3,864,325 | 02/04/75 | Smyth | | | |
| | 3,868,356 | 02/25/75 | Smyth | | | , |
| | 3,868,357 | 02/25/75 | Smyth et al. | | | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB CLASS | | LATION /NO |
|---------------------|--------------------|----------|---------------|-------|--------------|---|---------------|
| 86 | 214 826 A2 | 08/29/86 | EPO | | | x | |
| | 383 472 A2 | 02/06/90 | EPO | | • | x | |
| | 1,260,963 | 01/19/72 | Great Britain | | | x | |
| | 1,415,333 | 11/26/75 | Great Britain | | - | х | |
| | 1,492,997 | 11/23/77 | Great Britain | | | х | |
| | 1-254,699 | 11/11/89 | Japan | | | х | |
| 4 | WO 92/01476 | 02/06/92 | PCT | | | x | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| BP | Anderson, et al., "The Use of Esters of N-Hydroxysuccinimide in Peptide Synthesis," Journal of American Chemical Society, 86:1839-1842 (1964) |
|----|---|
| | Asada, et al., "Stability of Acyl Derivatives of Insulin in the Small Intestine: Relative Importance of Insulin Association Characteristics in Aqueous Solution," <i>Pharmaceutical Research</i> , <u>11</u> (8):1115-1120 (1994) |
| | Geiger, et al., "Contribution of Peptide Chemistry to our Knowledge of Insulin and Diabetes," from Proceedings of the Symposium on Proinsulin, Insulin and C-Peptide, Tokushima, July 12-14, pp. 62-72 (1978) |
| | Geiger, et al., "Biological Activity of Insulin Analogues Substituted at the Amino Group of B1-Phenylalanine, from Proceedings of the Second International Insulin Symposium, Aachen, Germany, September 4-7, pp. 409-415, (1979) |
| | Geiger, "Chemie des Insulins," Sonderdruck 100:111-129, (1976) (Translation Attached) |

| | | | _) _ ; |
|----------|---------------|-----------------|---------|
| EXAMINER | Road Dorokail | DATE CONSIDERED | 9/3/96 |
| | Dener Frickri | | |

EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.



| PTO-1449 (Modified) |
|---------------------|
|---------------------|

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 10361.49950

SERIAL NUMBER 08/484,542

APPLICANT

Mark L. Braden, et al.

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

FILING DATE June 7, 1995 GROUP ART UNITS

U.S. PATENT DOCUMENTS **DOCUMENT SUB FILING CLASS** NUMBER DATE NAME **CLASS** DATE 3,869,437 03/04/75 Lindsay 3,883,496 05/13/75 Geiger 3,883,500 05/13/75 Geiger et al. Geiger et al. 3,884,897 05/20/75 3,950,517 04/13/76 Lindsay, et al. 4,013,628 03/22/77 Obermeier 4,014,861 03/29/77 Geiger, et al. 5,304,473 04/19/94 Belagaje, et al.

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB CLASS | TRANSLATION YES/NO |
|---------------------|--------------------|------|---------|-------|--------------|-----------------------|
| | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|----|--|
| BD | Hashimoto, et al., "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities," <i>Pharmaceutical Research</i> , 6(2):171-176 (1989) |
| | Hashizume, et al., "Improvement of Large Intestinal Absorption of Insulin by Chemical Modification with Palmitic Acid in Rats," J. Pharm. Pharmacol., 44:555-559 (1992) |
| | Inoue, et al., "Synthesis of a Superoxide Dismutase Derivative That Circulates Bound to Albumin and Accumulates in Tissues Whose pH is Decreased," <i>Biochemistry</i> , 28(16):6619-6624 (1989) |
| | Kunitomo, et al., "Synthesis of Cytochrome c Derivative with Prolonged In Vivo Half-life and Determination of Ascorbyl Radicals in the Circulation of the Rat," The Journal of Biological Chemistry, 267(13):8732-8738 (1992) |
| | Lapidot et al., "Use of Esters of N-hydroxysuccinimide in the Synthesis of N-acylamino Acids," Journal of Lipid Research, 11(8):1115-1120 (1994) |
| | Lindsay et al., "Acetoacetylation of Insulin," Biochem. J., 115:587-595 (1969) |
| | Lindsay et al., "The Acetylation of Insulin," Biochem. J., 121:737-745 (1971) |
| | MacIntyre et al., "Information About Insulin by Chemical and Enzymatic Modifications," <i>Molecular Endocrinology</i> , Proceedings of Endocrinology '77 held at the Royal College of Physicians, London, England July 11-15, pp. 27-42 (1977) |
| | Muranishi, et al., "Trials of Lipid Modification of Peptide Hormones for Intestinal Delivery," Journal of Controlled Release, 19:179-188 (1992) |

| EXAMINER | Benet | Paroka | DATE CONSIDERED | 9/3/96 | | |
|--|-------|--------|-----------------|--------|--|--|
| EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant. | | | | | | |

PTO-1449 (Modified) ATTY. DOCKET NO. SERIAL NUMBER 10361.49950 08/484,542 U.S. DEPARTMENT OF COMMERCE APPLICANT PATENT AND TRADEMARK OFFICE Mark L. Braden, et al. FILING DATE INFORMATION DISCLOSURE STATEMENT BY APPLICANT June 7, 1995 U.S. PATENT DOCUMENTS DOCUMENT SUB **FILING** NUMBER DATE NAME **CLASS CLASS** DATE 4,839,341 06/13/89 Massey, et al. FOREIGN PATENT DOCUMENTS TRANSLATION **EXAMINER** DOCUMENT **SUB** INITIAL NUMBER DATE COUNTRY **CLASS CLASS** WO 95/07931 03/23/95 PCT X OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Riordan, et al., "Acetylation," Methods of Enzymology, 25:494-499 (1972) Rösen et al., "A1-Modified Insulins: Receptor Binding and Biological Activity," Insulin Chemistry, Structure and Function of Insulin and Related Hormones from Proceedings of the Second International Insulin Symposium, Aachen, Germany, September 4-7, pp. 403-408 (1979) Scheider, "Ligand-Independent Activated State of Serum Albumin for Fatty Acid Binding," Journal of Physical Chemistry, 84(8):925-928 (1980) Howey, "[Lys(B28), Pro(B29]-Human Insulin A Rapidly Absorbed Analogue of Human Insulin," Diabetes, 43:396-402 (1994) Derewenda et al., "X-ray Analysis of the Single Chain B29-A1 Peptide-linked Insulin Molecule," J. Mol. Biol., 220:425-433 (1991) Brange, "Stability of Insulin: Studies on the Physical and Chemical Stability of Insulin in Pharmaceutical Formulation," Kluwer Academic Publishers, pp. 6-41 and references pp. 46-59. Brange, "Neutral Insulin Solutions Physically Stabilized by Addition of Zn2+," Diabetic Medicine, Novo Research Institute, Denmark, pp. 70-74 (1986) Brange, "Chemical Stability of Insulin. 1. Hydrolytic Degradation During Storage of Pharmaceutical Preparations," Novo Research Institute, Denmark, pp. 75-86 (1991) Brange, Chemical Stability of Insulin. 2. Formation of Higher Molecular Weight Transformation Products During Storage of Pharmaceutical Preparations," Novo Research Institute, Denmark, pp. 87-94 (1991) Brange, Chemical Stability of Insulin. 3. Influence of Excipients, Formulation, and pH," Novo Research Institute, Denmark, pp. 95-104 (1991) Brange, "Galenics of Insulin: The Physico-Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations," Novo Research Institute, Denmark, Springer-Verlag Berlin Heidelberg 1987 **EXAMINER** DATE CONSIDERED EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.

BEST AVAILABLE COPY